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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,449	09/21/2001	Troy Holland	BioCure 161	5786

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
06/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/960,449	HOLLAND ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,8-11,13-17,21-23,25 and 27-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8-11,13-17,21-23,25 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 02/02/2007.

Claims 1-4, 8-11, 13-17, 21-23, 25 and 27-29 are pending and included in the prosecution.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-4, 8-11, 13-17, 21-23, 25 and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of "the initiator not bound to another polymer" has introduced new matter situation that was not described in the specification as originally filed. Nowhere in the specification applicants have disclosed initiator not bound to another polymer or even disclosed any polymer other than the macromer in the hydrogel.

Response to Arguments

3. Applicant's arguments filed 02/02/2007 have been fully considered but they are not persuasive. Applicants argue that the specification does not disclose initiator bond to macromer.

In response to this argument, it is argued that even the specification does not teach that the initiator is bound to the macromer, but it does not also teach that the initiators is not linked to another polymer, neither disclosed what are those another polymer. It is the examiner's duty to determine exactly what subject matter is encompassed by the claims. See, *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003). The present claims encompass initiator not bond to the macromer or unable to bound to any other polymer. Nowhere applicants have disclosed such an initiator. The disclosure is not commensurate with the scope of protection sought by the claims.

The Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation'." *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed.Cir. 1993).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 2, 8, 9 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,007,833 (833).

The scope of claims 1 and 29 is liquid composition comprising water soluble PVA having one or more pendant crosslinkable acrylamide groups. The intended use of the composition for spray delivery is not given weight in a claim directed to a composition.

US '833 teaches a hydrogel wound dressing that is applied to the wound site as a liquid composition and forms flexible polymeric matrix upon exposure to light, i.e. hydrogel formed *in situ* (col.10, lines 1-6). The hydrogel composition comprising crosslinkable macromer includes two or more polymer pendant polymerizable group (abstract). The macromer includes water-soluble polymer, i.e. degradable, as polyvinyl

alcohol; and acrylamide as a pendant polymerizable group (col.5, lines 25-30, 47-53). Acrylamide groups contain olefinically unsaturated groups. The hydrogel comprises therapeutic agent including growth factor, antimicrobial agent and antithrombotic agent (col.10, lines 11-12, 35-37). On col. 15, lines 28-31 of US '833, the reference teaches that the initiator can be polymer-bound or non-polymer bound solution.

However, US '833 teaches that the polymer-bound initiator forms matrices more rapidly and more completely than the non-polymer-bound initiator when exposed to light energy.

The disclosed examples and preferred embodiment do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a hydrogel composition comprising crosslinkable PVA macromer having one or more polymer pendant polymerizable group of acrylamide as disclosed by US '833, and use the non-polymer-bound initiator as disclosed by the

reference since the non-polymer-bound initiator disclosed to be slower in initiating matrices forming when exposed to light energy, and applicants desired to delay the matrices formation till the composition is sprayed, with reasonable expectation to have hydrogel composition comprising crosslinkable PVA macromer includes one or more polymer pendant polymerizable group of acrylamide and cross-linking initiator that is non-polymer-bound to provide delayed cross-linking when exposed to light until the hydrogel is used.

Response to Arguments

7. Applicant's arguments filed 02/02/2007 have been fully considered but they are not persuasive. Applicants traverse the above rejection by arguing that US '833 teaches that "preferably, the initiators are bound to the macromer". The reference does not teach the spray delivery of the composition.

In response to the above applicants' arguments, the examiner position is that the reference disclosed the initiator group is present as either a pendent group on a polymerizable macromer, or pendent on separate, non-polymerizable polymer backbone, i.e. not bound to the macromer (co1.4, lines 50-53). On col. 15, lines 28-31 of US '833, the reference teaches that the initiator can be polymer-bound or non-polymer bound solution. The reference further disclosed that the initiator can be bound to the polymeric backbone, and the expression "can be" indicates that the initiator also can not be bound to the polymer backbone. The disclosed examples and preferred

embodiment of the prior art do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi* 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

In response to applicant's argument that the recitation of "spray delivery" is not disclosed by the reference, the examiner is pointing out to that the limitation has not been given patentable weigh because the recitation occurs in the preamble and is directed to the method of using the composition as a spray. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The recitation of the such intended use in the claim permeable does not limit the scope of the claim since such statement merely define the context in which the invention operates, and the body of the claim defined the subject matter of the claimed invention. The claims are directed to composition, and all the elements of the composition are recited in the body of the claim, and the permeable is not essential to understand limitations or terms in the claim body and does not provide antecedent basis for terms in the body of the claim. The reference teaches liquid composition that forms hydrogel in situ, therefore it is applied as liquid and can be applied by any methods known to apply liquids including spray.

8. Claims 3, 4, 10, 11, 13-17, 21-23 25, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,007,833 ('833) in view of US 6,179,862 ('682).

US '833 teaches a hydrogel wound dressing that is applied to the wound site as a liquid composition and forms flexible polymeric matrix upon exposure to light, i.e. hydrogel formed *in situ* (col.10, lines 1-6). The hydrogel composition comprising crosslinkable macromer includes two or more polymer pendant polymerizable group (abstract). The macromer includes water-soluble polymer, i.e. degradable, as polyvinyl alcohol; and acrylamide as a pendant polymerizable group (col.5, lines 25-30, 47-53). Acrylamide groups contain olefinically unsaturated groups. The hydrogel comprises therapeutic agent including growth factor and antimicrobial agent (col.10, lines 11-12). On col. 15, lines 28-31 of US '833, the reference teaches that the initiator can be polymer-bound or non-polymer bound solution.

US '833 does not teach the composition is delivered by spray as claimed in claims 3, 4, 14-17, 21-22. The reference does not teach the active agent as NO as claimed in claims 10 and 23, or the redox irradiation as claimed in claims 13 and 25. The reference does not teach the dressing debrides the wound when removed as claimed in claim 12.

However, US '833 teaches the liquid delivery of the composition without excluding or specifying any method of delivery, thus the spraying the liquid composition into the wound is inclusive in the reference teaching. The reference also teaches the delivery of antithrombotic drugs at the site of application, and this is inclusive to NO, and one having ordinary skill in the art would have determined the antithrombotic agent to use according to the specific patient condition. The reference further teaches the UV irradiation to initiate polymerization. The reference disclosed that the wound dressing

formed is very well adheres to the wound site, and it is expected upon its removal to debride the wound.

US '862 disclosed method and composition for forming *in situ* tissue adherent barrier using sprayer to apply cross-linkable two components to the tissue that enable to form coating on the tissue surface (abstract; col.1, lines 48-51, 65-67; col.2, lines 1-8). When the sprayer is activated, the emergent spray contacts tissue, resulting in mixing and cross-linking of the components to form coating, e.g. hydrogel, on the tissue surface (col.2, lines 5-9). The components are in the form of solution and comprise water-soluble, crosslinkable, biodegradable macromers (col.2, lines 19-34; col.7, lines 24-30). The hydrogel formation is initiated by redox irradiation to form coating (col.4, lines 24-27; col.6, lines 3-5).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a hydrogel composition comprising crosslinkable PVA macromer includes one or more polymer pendant polymerizable group of acrylamide as disclosed by US '833 and deliver the composition by spraying and use redox for crosslinking as disclosed by US '862, motivated by the teaching of US '862 that the spraying on the tissue surface followed by redox irradiation enable to form a wound coating, with reasonable expectation of having a hydrogel composition comprising crosslinkable macromer includes one or more polymer pendant polymerizable group that is delivered from sprayer and polymerized by redox irradiation that enables to protect the wound and initiate wound healing with success.

Response to Arguments

9. Applicant's arguments filed 02/02/2007 have been fully considered but they are not persuasive. Applicants traverse the above rejection by arguing that US '833 does not teach the spray deliver, and US ' 862 does not teach the macromer used in the present invention which PVA. None of the references teaches the cross-linking initiator not bound to the macromer/polymer. The combination of the teachings of the references does not teach the claimed invention because US '833 teaches away. Applicants argue that neither any of the references teach pump spray delivery as claimed by claims 4 and 17, nor delivery of nitric oxide as claimed by claims 10 and 23.

In response to these applicants' arguments, the examiner position is that a conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. In re Bozek, 163 USPQ 545 (CCPA 1969). US '833 as stated above teaches the initiator can be not bound to the macromer, and US '862 teaches at co1.6, lines 3-7 the same initiator system disclosed by the applicants. Further, US '862 disclosed macromers in general, and it is relied upon for teaching the initiator system and the spray delivery recited in the method claim 14. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In considering the disclosure of the

reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. In re Preda, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). In this case, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a hydrogel composition comprising crosslinkable PVA macromer includes one or more polymer pendant polymerizable group of acrylamide as disclosed by US '833 and deliver the composition by spraying and use redox for crosslinking as disclosed by US '862, motivated by the teaching of US '862 that the spraying on the tissue surface followed by redox irradiation enable to form a wound coating, with reasonable expectation of having a hydrogel composition comprising crosslinkable macromer includes one or more polymer pendant polymerizable group that is delivered from sprayer and polymerized by redox irradiation that enables to protect the wound and initiate wound healing with success.

In response to applicant's argument that US '833 teaches away, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, US '833 in the same field of applicants' endeavor and also pertinent to applicants' problem which is the hydrogel wound treatment that is formed in situ. Further, US '833 suggests both bound and unbound initiator as set forth in this office action.

Regarding pump spray claimed by claims 4 and 17, applicants failed to show superior and unexpected results obtained from pump spray over gas spray disclosed by applicant.

With regard to NO claimed by claims 10 and 23, US '833 teaches the delivery of antithrombotic drugs at the site of application, and this is inclusive to NO, and one having ordinary skill in the art would have determined the antithrombotic agent to use according to the specific patient condition. NO recitation does not impart patentability to the claims, absent evidence to the contrary.

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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